

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BAUSCH & LOMB INCORPORATED & )  
PF CONSUMER HEALTHCARE 1 LLC, )

Plaintiffs, )

v. )

SBH HOLDINGS LLC, )

Defendant. )

Civil Action No. 20-1463-GBW-CJB

**MEMORANDUM ORDER**

In this patent action filed by Plaintiffs Bausch & Lomb Incorporated and PF Consumer Healthcare 1 LLC (“Plaintiffs”) against Defendant SBH Holdings LLC (“SBH” or “Defendant”), Plaintiffs allege infringement of United States Patent Nos. 6,660,297 (the “’297 patent”) and 8,603,522 (the “’522 patent” and collectively with the ’297 patent, “the asserted patents”). Presently pending is Plaintiffs’ *Daubert* motion seeking to exclude the expert opinion and testimony of Dr. Matthew Kaser, filed pursuant to Federal Rule of Evidence 702 (the “Motion”). (D.I. 158) SBH opposes the motion. For the reasons that follow, the Court hereby ORDERS that Plaintiffs’ Motion is GRANTED.

**I. BACKGROUND**

Plaintiffs filed this action on October 28, 2020. (D.I. 1) This case has been referred to the Court by United States District Judge Gregory B. Williams to resolve all pre-trial matters up to and including summary judgment motions, pursuant to 28 U.S.C. § 636(b). (D.I. 40; D.I. 143)

Plaintiffs filed the instant Motion on September 3, 2024. (D.I. 158) The Motion was fully briefed as of November 7, 2024. (D.I. 227) A trial is set to begin on April 21, 2025. (D.I. 241)

The Court here writes primarily for the parties, and so any facts relevant to this Memorandum Opinion will be discussed in Section III below.

## **II. STANDARD OF REVIEW**

The Court has frequently set out the relevant standard of review for assessing a motion, like this one, filed pursuant to Rule 702 and *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579 (1993). One such instance came in *Integra LifeScis. Corp. v. HyperBranch Med. Tech., Inc.*, Civil Action No. 15-819-LPS-CJB, 2018 WL 1785033, at \*1-2 (D. Del. Apr. 4, 2018). The Court incorporates by reference these legal standards set out in *Integra*, and will follow them herein. To the extent that additional related legal principles regarding Rule 702 and *Daubert* are relevant, the Court will set those out in Section III.

## **III. DISCUSSION**

Dr. Kaser is SBH's technical expert regarding infringement and prosecution history estoppel. (See D.I. 166, ex. 6 at ¶ 2) With their Motion, Plaintiffs raise three issues with Dr. Kaser's opinions: (1) that Dr. Kaser lacks the necessary qualifications for his opinions related to the perspective of a person of ordinary skill in the art ("POSITA") because he does not meet the minimum level of skill for a POSITA; (2) that Dr. Kaser's prosecution history estoppel opinions should be excluded because they are based on theories that the Court has considered and rejected during claim construction; and (3) that Dr. Kaser's opinions relating to the claim limitation "approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof" should be excluded as contrary to the Court's claim construction. (D.I. 165 at 2, 33-42; D.I. 227 at 21-24) For the reasons set out below, the Court agrees with Plaintiffs' first argument; because that argument implicates all of the portions of Dr. Kaser's rebuttal report that Plaintiffs seek to strike

with their remaining arguments, the Court need not address those arguments in order to resolve the Motion.<sup>1</sup>

Below, the Court will first set out additional relevant legal standards for assessing an expert's qualifications in this context. Next, the Court will summarize the parties' respective arguments. Lastly, it will explain its reasoning as to why the Motion should be granted.

#### **A. Legal Standards Regarding Expert Qualifications**

In terms of expert qualifications, the United States Court of Appeals for the Third Circuit has explained that an inquiry under Rule 702 must address whether the expert witness has “specialized knowledge’ regarding the area of testimony.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (quoting *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998)). The basis of this specialized knowledge may be “practical experience as well as academic training and credentials.” *Id.* (internal quotation marks and citations omitted). At a minimum, however, “a proffered expert witness . . . must possess skill or knowledge greater than the average layman[.]” *Id.* (internal quotation marks and citations omitted). The Third Circuit has tended to apply this standard liberally. *Id.*; see also *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003).

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<sup>1</sup> Despite what the Court has said above, in their briefing, Plaintiffs asserted that their third argument also implicates paragraphs 92-95 of Dr. Kaser's rebuttal report—and those four paragraphs are not among the paragraphs that Plaintiffs list as being relevant to their first argument (i.e., the one addressed herein). (See D.I. 165 at 37-38, 42) Nevertheless, this will not require the Court to delve into the third argument here. That is because Dr. Kaser's report does not actually appear to include any paragraphs with numbers 92, 93 or 94. (D.I. 166, ex. 6 at 29-32) And paragraph 95 in his report simply includes a recitation of certain claim language. (*Id.* at 31-32) Therefore, there is no need for the Court to separately address any argument pertaining to those four particular paragraphs.

Additionally, the United States Court of Appeals for the Federal Circuit<sup>2</sup> has explained that “[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for . . . validity[] or infringement—a witness must at least have ordinary skill in the art.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022); *see also Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1340 (Fed. Cir. 2024). “Without that skill, the witness’ opinions are [also] neither relevant nor reliable. The opinions would not be based on any specialized knowledge, training, or experience that would be helpful to the factfinder.” *Kyocera*, 22 F.4th at 1377; *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1362 (Fed. Cir. 2008) (“Admitting testimony from a person . . . with no skill in the pertinent art[] serves only to cause mischief and confuse the factfinder.”).<sup>3</sup>

## **B. The Parties’ Arguments**

With the relevant law set out, the Court turns to the parties’ arguments. To that end, in their reports, the parties’ technical experts—Dr. Elizabeth Johnson for Plaintiffs and Dr. Kaser for Defendant—*agreed* on the definition of a POSITA. (*See* D.I. 166, ex. 5 at 46-48 (Dr. Kaser noting that Dr. Johnson’s definition of a POSITA used “similar language” as did his definition,

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<sup>2</sup> The Federal Circuit has noted that “[p]atent cases, like all other cases, are governed by Rule 702. There is, of course, no basis for carving out a special rule as to experts in patent cases.” *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008). That Court applies the law of the otherwise applicable regional circuit to issues (including issues relating to expert testimony) that are not unique to patent law; as to issues unique to patent law, the Federal Circuit applies its own precedent. *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1294 (Fed. Cir. 2015).

<sup>3</sup> To the extent that Defendant argues that an expert need not meet the parties’ definition of a POSITA in order to testify from the perspective of a POSITA, (D.I. 207 at 49), Defendant ignores cases such as *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369 (Fed. Cir. 2022) and *Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335 (Fed. Cir. 2024), which very clearly say just that.

and indicating that he agrees with Dr. Johnson's definition); *see also* D.I. 165 at 35 n.7) Dr.

Kaser defined a POSITA as follows:

A POS[IT]A at the time of the inventions would be: a medical doctor, doctor of optometry ("O.D.") or a person with a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry, or a related discipline *and experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD.* [Alternatively, a POS[IT]A at the time could have been a person with a Bachelor's degree with a greater number of years of experience. The POS[IT]A would have, or would have access to, general information regarding AMD, the convenience and needs of patients who suffer from AMD, and background information.

(D.I. 166, ex. 6 at ¶ 19 (emphasis added) (the "POSITA definition")) Dr. Johnson's definition of a POSITA was mostly the same; she included in her definition that the POSITA "would typically have been a medical doctor, doctor of optometry ('O.D.') or a person with a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry or a related discipline *and a few years of practical experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD.*" (*Id.*, ex. 4 at ¶ 29 (emphasis added))

The parties' dispute here, as it has been presented to the Court, is about how to *properly interpret the agreed-upon definition* of a POSITA. (D.I. 207 at 50 (Defendant accusing Plaintiffs of making a "complete contortion of the POS[IT]A definit[ion] proffered"); D.I. 227 at 22 (Plaintiffs responding that Defendant and Dr. Kaser provide a "strained reading of the agreed upon definition of a POS[IT]A")) More specifically, the question presented to the Court is whether that agreed-upon definition, rightly interpreted, requires a POSITA to have at least some *experience* in the relevant art. And the answer to that question, in turn, impacts whether Dr.

Kaser is qualified to offer testimony about infringement in this case. The Court sets out the parties' respective positions on this dispute below.<sup>4</sup>

On the one hand, Plaintiffs argue that the POSITA definition includes two requirements: (1) an education prong; and (2) an experience prong (i.e., one that requires “experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD”). (D.I. 165 at 35-38; D.I. 227 at 21-23) And they assert that Dr. Kaser does not qualify as a POSITA because he does not meet the experience prong of the POSITA definition. (D.I. 165 at 35-38; D.I. 227 at 21-23) That is, Plaintiffs contend that the POSITA *must* have (in addition to the required educational background set out in the definition) “experience in the nutritional supplement area” and “an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD”—but that Dr. Kaser’s experience does not align with this requirement. (D.I. 165 at 35-38; D.I. 227 at 21-23) Any argument to the contrary is nonsensical, according to Plaintiffs, because the POSITA definition understandably “requires those with advanced degrees, regardless of the specialty, to also have at least some experience in the

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<sup>4</sup> In other words, with the Motion, the parties have simply presented the Court with a dispute about what the agreed-upon POSITA definition *means*. And so the Court is resolving the dispute that the parties have presented to it (and, relatedly, the instant Motion) based on the record before it. To the extent that the parties might also have had an underlying substantive, factual dispute regarding the definition of a POSITA (e.g., with regard to what is the required amount of experience needed to qualify as a POSITA, and why), they did not sufficiently brief or present any such dispute to the Court. *See, e.g., Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (explaining that the obviousness analysis can implicate numerous factual inquiries, including “the level of ordinary skill in the prior art[.]” and that “[f]actors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field”) (internal quotation marks and citations omitted). And so the Court has not addressed any such issue herein.

relevant art”—“[t]he only logical reading of this definition would require a POS[IT]A in this case to have some experience with nutritional supplements, some understanding of formulations designed to prevent or treat visual acuity loss in patients diagnosed with AMD, and some information regarding AMD.” (D.I. 227 at 22)

On the other hand, Defendant interprets the POSITA definition as requiring (as relevant to the parties’ dispute here) *either*: “[1.] a medical doctor, doctor of optometry (‘O.D.’) or a person with a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry *or* [2. a person holding such a degree in] a related discipline and [having] experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD.” (D.I. 166, ex. 6 at ¶ 19 (emphasis added); D.I. 204 at ¶ 2; D.I. 207 at 35, 48-50) In other words, Defendant’s position is that if a person is a medical doctor or doctor of optometry, or if the person has an advanced degree in nutritional science, chemistry, biology or biochemistry, then he or she does *not* need to have any “experience in the nutritional supplement area” in order to qualify as a POSITA under the POSITA definition—one would *only* need such experience if he or she had an advanced degree in a “related discipline[.]” (D.I. 204 at ¶ 2; D.I. 207 at 35, 48-50) Because Dr. Kaser has a master’s degree and a Ph.D. in biochemistry, full stop, Defendant asserts that he meets the POSITA definition. (D.I. 207 at 35, 50)<sup>5</sup>

### C. Analysis

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<sup>5</sup> Dr. Kaser submitted a declaration in which he states that the explanation above of Defendant’s position comports with his own understanding of the POSITA definition; he states that he is a POSITA under this definition, since he holds Master’s and Ph.D. degrees in biochemistry. (D.I. 204 at ¶ 2 (“I certainly would not agree that a POS[IT]A at the time of the invention involved in this lawsuit would have to be a person with experience in formulations aimed at preventing or treating visual acuity loss in patients diagnosed with AMD.”))

With the parties' arguments explained, the Court lastly turns to the merits.

In so doing, the Court first addresses the parties' respective interpretations of the POSITA definition. It easily agrees with Plaintiffs' interpretation, for at least three reasons.

First, Plaintiffs' position better comports with a common sense understanding of what it means to be a person of skill in a relevant art. To that end, both parties' technical experts have explained that the asserted patents "relate to the art of nutritional supplement compositions for eye health and their methods of use." (D.I. 166, ex. 4 at ¶ 28; *id.*, ex. 6 at ¶ 18) Thus, it makes logical sense that to qualify as a person of ordinary skill *in the art* at the time of the invention, a person would need to have some familiarity *with that art*—i.e., some experience in the nutritional supplement area, including an understanding of formulations used to prevent or treat visual acuity loss. (D.I. 227 at 22); *cf. Chung v. Vaporous Techs., LLC*, 2:16-cv-08586-RSWL-PLA, 2018 WL 566782, at \*4 (C.D. Cal. Jan. 25, 2018) (noting in resolving a claim construction dispute that a party's expert with no "experience with electronic cigarettes or any of the patented products that form the basis of his opinions" could not be considered to be a POSITA of the relevant inventions).

Second, the actual wording of the POSITA definition aligns with Plaintiffs' position. For example, the definition states that as an alternative to someone with an advanced degree, "a POS[IT]A at the time could have been a person with a Bachelor's degree *with a greater number of years of experience*." (D.I. 166, ex. 6 at ¶ 19 (emphasis added)) This additional language clearly conveys that the POSITA definition includes two types of requirements—a degree-related prong and an experience-related prong—and that it means to utilize a type of sliding scale approach as to how one can satisfy each of those prongs. More specifically, the definition articulates that a POSITA with an advanced degree (i.e., a medical doctor, or an O.D., or a



person with a Master's or Ph.D. in certain fields) is also required to have at least *some* number of years of experience in the nutritional supplement area. But the definition goes on to explain that, alternatively, if the person has a lesser degree than the types of degrees referenced above (i.e., a Bachelor's degree), then in order to qualify as a POSITA, the person will need to have a *greater* number of years of relevant experience in the field. (*See* D.I. 227 at 22)<sup>6</sup>

Third, Dr. Kaser's testimony during his deposition supports Plaintiffs' position. During the deposition, Dr. Kaser was questioned about the experience prong of the POSITA definition. In response, he did not take the position that a POSITA would not need to have *any* experience in the nutritional supplement field—so long as he or she was a medical doctor or doctor of optometry, or had an advanced degree in nutritional science, chemistry, biology or biochemistry. (D.I. 228, ex. 3 at 49 (*cited in* D.I. 227 at 22-23)) Instead, when asked “[w]hat type of experience in the nutritional supplement area would your [POSITA] possess?” Dr. Kaser responded that he would expect the POSITA to have obtained experience through “a research program [in nutrition] at a university or clinically related” program. (*Id.* at 49-50)<sup>7</sup>

With it thus settled that the POSITA definition requires experience in the nutritional supplement area—including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD—that leaves the question of

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<sup>6</sup> Moreover, Defendant never explains why being any type of “medical doctor” or having any advanced degree in chemistry, for example, would not require any experience in the nutritional supplement area—but having an advanced degree in a “related discipline” *would* require such experience.

<sup>7</sup> Dr. Kaser went on to say that he was unsure of exactly how many years of experience such a person would need to have in this area in order to qualify as a POSITA. (D.I. 228, ex. 3 at 49)

whether Dr. Kaser *has* such experience. Tellingly, Defendant does not even try to make this showing.

For example, in its briefing, Defendant says only that Dr. Kaser “did post-doctoral research and patent work at a pharmaceutical company” (without citing to anything in support). (D.I. 207 at 35; *see also id.* at 49-50 (Defendant arguing only that Dr. Kaser is qualified because of his degrees and his experience as a patent agent and as a lecturer at a university)) Defendant thus pointed to no record evidence in its briefing suggesting that this “post-doctoral research” and/or “patent work” related in any way to the nutritional supplement area.

And in his declaration, Dr. Kaser did not provide any other “details of any experience in the field of nutritional supplements for eye health and their methods of use.” (D.I. 227 at 23) Instead, the declaration simply refers to paragraph 20 of Dr. Kaser’s rebuttal report in order to describe his qualifications as a POSITA. (D.I. 204 at ¶ 3) Paragraph 20 of Dr. Kaser’s rebuttal report, in turn, recites Dr. Kaser’s degrees, notes that he teaches “Comparative Physiology and Endocrinology” to undergraduate and graduate students, and states that he worked after college as a research technician at the University of Oxford’s Department of Biochemistry (with training that involved “being able to successfully prepare samples, buffer solutions, standardize biochemical assays, measure extremely small quantities of compounds for experiments, such as treatment of cell cultures and enzyme assays”). (D.I. 166, ex. 6 at ¶ 20) Nothing in Paragraph 20 conveys to the Court that Dr. Kaser has experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD.

Therefore, Defendant—the party that has the burden to demonstrate by a preponderance of proof that Dr. Kaser meets the standards for admissibility, *see Mercedes-Benz USA, Inc. v.*

*Coast Auto. Grp., Ltd.*, 362 F. App'x 332, 335 n.2 (3d Cir. 2010)—has failed to show that Dr. Kaser meets the POSITA definition,<sup>8</sup> *see, e.g., Kyocera*, 22 F.4th at 1376-78 (finding that the court abused its discretion in admitting an expert's testimony regarding any issue analyzed through the lens of a POSITA, where the "level of ordinary skill in the art, adopted during claim construction, requires experience in power nailer design" and the expert, while having advanced degrees in engineering and extensive experience in the design and manufacture of fastener driving tools, lacked experience in power nailer design); *Takeda Pharm. Co. Ltd. v. Norwich Pharms., Inc.*, Civil Action No. 20-8966 (SRC), 2022 WL 17959811, at \*33 (D.N.J. Dec. 27, 2022) (finding that "it is proper to exclude" the expert's testimony on any "salt-related topic" where the expert had opined that a POSITA would routinely perform a salt screen, while also

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<sup>8</sup> *Plaintiffs'* briefing reveals that the extent of Dr. Kaser's experience with the nutritional supplement area consists of: (1) "[p]erhaps two to three hours" of an undergraduate college lecture; (2) his mother having AMD and his understanding that she was taking supplements and was undergoing eye injections; and (3) a few months of working with scientists in order to draft a patent application. (D.I. 166, ex. 5 at 56-58, 60 (*cited in* D.I. 165 at 35-36)) *Plaintiffs'* briefing also notes that Dr. Kaser could not identify anything that he learned about "formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD" beyond what he learned through his work as an expert in this case. (*Id.* at 61-62 (*cited in* D.I. 165 at 36))

But as noted above, *Defendant* did not even cite to any of this information in attempting to assert that Dr. Kaser had the requisite qualifications to be a POSITA in this case. And none of the above-referenced experience amounts to experience gained in a "research program at a university or clinically related" program in the area of nutrition, which is the level of experience that Dr. Kaser himself identified as being relevant to the POSITA definition. (D.I. 228, ex. 3 at 50) Nor does the above-referenced experience appear to come close to "a few years of practical experience" as required by Dr. Johnson's POSITA definition (which, as noted above, Dr. Kaser agreed with). (D.I. 166, ex. 4 at ¶ 29) The Court therefore cannot conclude that any of this rises to the level of the requisite experience in the field of the invention. *See, e.g., NorthMobileTech LLC v. Simon Prop. Grp., Inc.*, 11-cv-287-wmc, 2012 WL 12996205, at \*3 (W.D. Wis. July 9, 2012) (finding that an expert did not qualify as a person of ordinary skill in the art with respect to marketing matters, where the record conveyed that he had "very little or no marketing experience").

acknowledging that he had never performed a salt screen and therefore he “does not meet his own definition of a POS[IT]A”), *aff’d*, 2023-1374, 2023 WL 3244022 (Fed. Cir. May 4, 2023); *Bial-Portela & CA. S.A. v. Alkem Lab’ys Ltd.*, Civ. No. 18-304-CFC-CJB, 2022 WL 4244989, at \*6-7 (D. Del. Sept. 15, 2022) (excluding testimony of experts regarding their ultimate conclusions of validity and underlying technical questions because they did not meet the relevant POSITA definition). Because Dr. Kaser does not have the experience required of the parties’ POSITA definition, the Court GRANTS Plaintiffs’ Motion requesting that all of Dr. Kaser’s testimony related to the perspective of the POSITA be excluded. (D.I. 165 at 34)<sup>9</sup>

#### IV. CONCLUSION

For the reasons set out above, the Court hereby ORDERS that Plaintiffs’ Motion is GRANTED.

Dated: February 24, 2025

  
Christopher J. Burke  
UNITED STATES MAGISTRATE JUDGE

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<sup>9</sup> Plaintiffs identify these opinions as paragraphs 32, 61-90, 105-142, 150 and 154 (opinions concerning Defendant’s infringement of the patents, including under the doctrine of equivalents); paragraphs 21-46, 63, 65, 67-79 and 154 (opinions regarding how a POSITA would understand the specification and prosecution history, including with respect to prosecution history estoppel); and paragraphs 28-31, 63-65, 91 and 96-104 (opinions regarding how a POSITA would interpret the claims). (D.I. 165 at 34 & n.6, 37-38) Defendant does not dispute that these paragraphs relate to the perspective of the POSITA.